K123468

510(k) Summary

SYBRON DENTAL SPECIALTIES

MAR 20 2013

Submitter:

Sybron Dental Specialties, Inc.
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Orange, California 92867
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Colleen Boswell - Contact Person

Date Summary Prepared: November 2012

- Trade Name – *Demi Ultra*
- Common Name – L.E.D. Curing Light
- Classification Name – Ultraviolet activator for polymerization, per 21 CFR 872.6070
- Product Codes – Ultraviolet activator for polymerization (EBZ)

Devices for Which Substantial Equivalence is Claimed:

- *Demi*, Kerr Corporation, K071251

Device Description

The *Demi Ultra* is a Light Emitting Diode (LED) visible light curing device used for the polymerization of light-cured materials by dental professionals. The *Demi Ultra* consists of a handpiece, LED light curing attachment, and charging dock. The aluminum and plastic molded handpiece contains two (2) ultracapacitors (electric double-layer capacitors), printed circuit boards containing the electronics and user interface buttons, receptacle for retaining the LED light curing attachment, and receptacle for interfacing with the charging dock. The LED light curing attachment contains the curing LED, clear lens and two (2) copper head spreaders, all over molded in plastic. The charging dock contains printed circuit boards containing electronics to support charging the handpiece and built-in LED radiometer functionality. For the handpiece, a digital circuit and microprocessor is utilized to control three (3) different curing modes (5, 10 and 20 seconds). Each mode specifies LED curing output and optional audible beep timing. The handpiece uses one button to activate the LED curing output and another to select the curing time mode. For the charging dock, a digital circuit and microprocessor is utilized to monitor the charging of the handpiece ultracapacitors, as well as respond to light at the radiometer input by illuminating lights on a radiometer meter.

Indications for Use

The *Demi Ultra* is a Light Emitting Diode (LED) visible light curing device used for the polymerization of light-cured materials by dental professionals.

Summary of Technological Characteristics

Descriptive Information	***Demi Ultra***	**Demi (K071251)**
Company	**Kerr Corporation**	Kerr Corporation
Indication for Use	**The *Demi Ultra* is a Light Emitting Diode (LED) visible light curing device used for the polymerization of light-cured materials by dental professionals.**	The *Demi* is a Light Emitting Diode (LED) visible light curing device used for the polymerization of light-cured materials by dental professionals.
Cordless	**Yes**	Yes
Light Source	**LED**	LED
Handpiece powersource	**Ultracapacitor**	Battery
AC supply connection	**100-240V AC, 1.0-0.5A, 50-60 Hz**	100-240V AC, 0.8-0.4A, 47-63 Hz
Operating time	**4 minutes**	50 minutes
Built-in radiometer	**Yes**	No
Microprocessor control	**Yes (8-bit uc)**	Yes (8-bit uc)
Power status indicator	**Yes**	Yes
Standard light guide	**8mm tapered**	8mm tapered
Reusable light guide	**Yes**	Yes
User replaceable power source	**No**	Yes
Handpiece digital display	**No (LED indicators)**	No
User selectable curing modes	**Yes (5, 10 & 20 seconds)**	Yes (5, 10 & 20 seconds)
Cooling fan	**No**	Yes
Audible beep	**Yes**	Yes
Continuous curing	**Yes**	Yes
Power source	**Two (2) Ultracapacitors**	Lithium Ion battery
Handpiece	**Valox 357U**	Valox 357U
Charging Base	**Valox 357U**	Valox 357U
Peak wavelength	**450-470nm**	450-470nm
Wavelength range @ 50% (spectrum)	**438-485nm**	438-485nm
Typical output intensity: 400-500nm, using 8mm turbo light guide	**1100mW/cm^2 pulsed to 1330mW/cm^2**	1100mW/cm^2 pulsed to 1330mW/cm^2

Descriptive Information	*Demi Ultra*	Demi (K071251)
EMC	**IEC66601--1-2:2007, EN 60601-1-2:2007, and JIS T 0601-1-2:2012**	IEC66601-1-2:2001
Safety	**AAMI ES60601-1 and CSA C22.2#60601-1**	AAMI ES60601-1 and CSA C22.2#60601-1

Non-Clinical Test Data

Biocompatibility data is available on the material designed to be in contact with a patient. Included in this submission are statements from the material manufacturer indicating that samples from typical production lots were subjected to the biocompatibility tests and passed.

This 510(K) submission also includes depth of cure test data used to evaluate the performance of the *Demi Ultra* as compared to the predicate device. Also included is irradiance data which demonstrates light intensity and peak wavelength.

The *Demi Ultra* software has been successfully validated to confirm the performance of the device.

Clinical Test Data

Clinical testing has not been conducted on this product.

Conclusion

Based upon the biocompatibility studies, similar technological/performance characteristics as compared to the predicate device, and successful validation of the *Demi Ultra* software, the performance of the *Demi Ultra* is deemed to be substantially equivalent to the *Demi*.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2013

Kerr Corporation
C/O Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
ORANGE CA 92867

Re: K123468
Trade/Device Name: Demi Ultra
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: January 3, 2013
Received: January 29, 2013

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123468

Device Name: *Demi Ultra*

Indications for Use:

The *Demi Ultra* is a Light Emitting Diode (LED) visible light curing device used for the polymerization of light-cured materials by dental professionals.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
2013.03.20
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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